Regulations for the Sale of Viruses, Serums, Toxins, and Analogous Products.

Treasury Department.
Washington, D. C., May 11, 1909.

The following regulations have been prepared by the undersigned board of officers in accordance with the provisions of section 4 of an act of Congress approved July 1, 1902, entitled "An act to regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes;" they are hereby promulgated and will supersede the regulations issued February 21, 1903, and amendments thereto.

G. H. Torney,
Surgeon-General, U. S. Army.
P. M. Rixey,
Surgeon-General, U. S. Navy.
Walter Wyman,
Surgeon-General, Public Health and Marine-Hospital Service.

Approved:
Franklin MacVeagh,
Secretary of the Treasury.

ISSUE OF LICENSES.

1. Licenses shall be issued, suspended, and revoked by the Secretary of the Treasury, upon the recommendation of the Surgeon-General of the Public Health and Marine-Hospital Service.

2. Licenses shall be issued only after inspection of establishments and examination of the products for which license is desired.

3. When an establishment shall have been inspected and the products propagated therein examined in accordance with these regulations, the report of inspection and laboratory examination shall be passed upon by the sanitary board of the Public Health and Marine-Hospital Service. The said board shall present its findings to the Surgeon-General of the Public Health and Marine-Hospital Service who shall review and forward same, together with his recommendations, to the Secretary of the Treasury for action.

4. The following form of license is prescribed:

LICENSE.

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This is to certify that....., of....., State of ....., have complied with the terms of "An act to regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes;" that the establishment of the said ..... has been duly inspected in accordance with regulations made under the terms of the said act, and that the said..... are hereby authorized to engage in the manufacture, barter, and sale of.....for one year from this date, or until reinspection.

This license is issued in accordance with the regulations prepared under the above-mentioned act, and is subject to suspension or revocation when due cause therefor is shown.

[L. S.]

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Secretary of the Treasury.

5. Licenses shall be good for one year from the date of issue (or until reinspection), and will not be reissued without such reinspection and laboratory examination; the report of inspection and laboratory examination to be passed upon by the sanitary board and the Surgeon-General of the Public Health and Marine-Hospital Service, in accordance with the provisions of paragraph 3. Inspections shall be made at least once a year.

INSPECTION OF ESTABLISHMENTS.

6. The inspection shall be made by an inspector or a board of inspectors detailed by the Secretary of the Treasury upon the recommendation of the Surgeon-General of the Public Health and Marine-Hospital Service.

7. The inspectors shall be commissioned medical officers of the Public Health and Marine-Hospital Service or chiefs of division of the hygienic laboratory of the same service.

8. The visit of the inspectors shall be unannounced.

9. It shall be the duty of the inspectors to call first upon the head of the establishment or member of the firm, stating the object of their visit.

10. The inspectors shall examine all portions of the premises, appliances, stables, barns, warehouses, records, and the methods employed in actual operation.

11. The inspectors are authorized, when they consider it necessary, to interrogate the proprietor, members of the firm, and employees of the establishment under oath.

12. The inspectors shall investigate fully the methods of preparation, storing, dispensing, and other details in the manufacture and sale of serums, viruses, toxins, and analogous products.

13. The inspectors shall carefully examine into faulty construction or administration of establishments which would tend to impair the potency or purity of their products, and shall, if of sufficient importance, make special report regarding the same.

14. It shall be the duty of the inspectors to purchase in open market or, if they deem it advisable, themselves to obtain in the establishment samples of the products then manufactured, which samples shall be examined by the inspectors for purity and potency or forwarded to the director of the hygienic laboratory for such examination.

15. It shall be the duty of the director of the hygienic laboratory of the Public Health and Marine-Hospital Service to test samples sent him by inspectors for purity and potency, and the result of this examination shall be given to the inspectors, who shall give this report due weight in making their recommendations.

EXAMINATIONS OF VIRUSES, SERUMS, TOXINS, ETC.

16. The terms "virus, serum, toxin, and analogous products" shall include the following products and such others as may be designated by the Secretary of the Treasury from time to time: Antidiphtheric serum or diphtheria antitoxin, antitetanic serum or tetanus antitoxin, antistreptococcic serum, antistaphylococcic serum, antigonococcic serum, antipneumococcic serum or antipneumonic serum, antidysenteric serum, antituberculous serum, antipest serum, anticholera serum, streptolytic and pneumolytic serum, antimeningococcic serum, antiplague serum, erysipelas and prodigiosus toxins, tuberculins, emulsion tubercle bacilli, suspension of lactic acid bacilli, antityphoid serum, bacterial vaccines, normal horse serum, and vaccine virus.

17. Viruses, serums, toxins, and analogous products propagated in licensed establishments and offered for sale in the District of Columbia, or in interstate traffic, shall be obtained from time to time in the open market and examined under the direction of the Surgeon-General of the Public Health and Marine-Hospital Service as to purity and potency and as to whether said products are properly labeled, as required by section one of the law.

18. Viruses, serums, toxins, and analogous products propagated in licensed establishments and imported from abroad will be detained by customs officers at ports of entry, pending examination by officers of the Public Health and Marine-Hospital Service as to purity and potency and as to whether said products are properly labeled as required by section 1 of the law.

19. Samples of the same laboratory numbers shall accompany each foreign importation of viruses, serums, toxins, and analogous products, and said samples will be forwarded by collectors of customs to the Surgeon-General of the Public Health and Marine-Hospital Service at Washington for examination.

20. Viruses, serums, toxins, and analogous products imported from foreign countries will be refused entry by collectors of customs unless propagated in an establishment holding an unsuspended and unrevoked license, or intended for examination precedent to obtaining a license.

21. The immunity unit for measuring the strength of diphtheria antitoxin shall be that established and distributed by the Public Health and Marine-Hospital Service.

22. The immunity unit for measuring the strength of tetanus antitoxin shall be ten times the least quantity of antitetanic serum necessary to save the life of a 350-gram guinea pig for ninety-six hours against the official test dose of a standard toxin furnished by the Hygienic Laboratory of the Public Health and Marine-Hospital Service.

23. Manufacturers placing on the market serums concentrated by Gibson's method or by any other method, or mixed serums made by

mixing concentrated serum with ordinary antitoxic serum, shall be required to so label them.

24. Preliminary to taking vaccine material from vaccinated animals, said animals should be killed or otherwise rendered insensible to pain.

25. As soon as practicable after taking the vaccine virus, a necropsy shall be made upon each animal, and permanent records kept of each necropsy, in which particular reference shall be made of pathologic changes.

26. All vaccine material from any animal having a communicable disease, other than vaccinia, or suspected of having a communicable disease, shall be destroyed.

27. The practice of renting animals for the purpose of propagating vaccine virus and returning the animals to the market shall be discontinued.

28. Animals used for propagating vaccine virus must be under daily veterinary inspection for not less than seven days immediately before they are vaccinated. Only healthy animals free from communicable disease shall be used for this purpose.

29. The propagation and sale in interstate traffic of old-style dry "lymph" vaccine points shall be discontinued after January 1, 1910.

30. Each and every lot of vaccine virus shall be examined to determine its freedom from pathogenic micro-organisms, and a special examination must be made of each and every lot to determine the absence of tetanus; detailed and permanent records of these examinations shall be kept by the establishment propagating said virus.

31. Containers, grinding and mixing machines, filling apparatus, instruments, etc., that come in contact with vaccine material during the process of manufacture and preparation for the market, shall be sterilized before use by steam under pressure at a temperature of at least 120° C. for not less than thirty minutes, or subjected to dry heat at a temperature of at least 160° C. for not less than one hour. Materials that will not stand this degree of dry heat shall be sterilized by a process known to be capable of destroying tetanus spores.

32. Refuse, wastes, excelsior, packing materials such as hay, straw, cotton, etc., crude materials and goods of miscellaneous origin and unknown history shall not be stored or permitted in or about vaccination stables or where the animals used for propagating vaccine virus are kept.

SUSPENSION AND REVOCATION.

33. When faulty methods of preparation, faulty construction, or administration of establishments are observed during inspection, the inspector shall bring the same to the attention of the manufacturer, and shall forward a report of the conditions found, together with his recommendations, to the Surgeon-General.

34. When impurities or lack of potency of products, or improper labeling of same shall be demonstrated by laboratory examination, these facts shall be reported to the Surgeon-General.

35. Should the faulty conditions discovered during inspection or laboratory examination be found upon review by the sanitary board

and the Surgeon-General to be of sufficient importance, the Surgeon-General shall recommend to the Secretary of the Treasury that the license of the offending establishment be suspended. If the said faulty conditions are not corrected within sixty days after suspension, he shall recommend that the said license be revoked.

36. The facts of suspension and revocation of licenses, with causes therefor, may be published in a circular to be issued and signed by the Secretary of the Treasury.

The above are revised regulations embodying amendments and additions that have been made from time to time to the first regulations issued February 21, 1903. In the revision new provisions have been made relating to administrative details, including particularly paragraphs relating to further safeguards in the propagation and sale of vaccine virus and a closer supervision over the importation of the same.

Recent investigations have demonstrated that foot-and-mouth disease may be transmitted to animals through vaccine virus, but whether the disease may be transmitted to man through this agency is doubtful, no case of such transmission being known. The investigations referred to were made by this service in cooperation with the Bureau of Animal Industry following an outbreak of this disease last November, and the results are published in Bulletin No. 147 of that bureau. The vaccine virus of two establishments was found to be contaminated and necessary measures were immediately taken. All possibly infected virus of these two firms was recalled from the market, destroyed, or held under government seal. In addition all necessary measures were taken to eradicate the infection from the establishments themselves. Until these requirements had been fulfilled, as was ascertained by three special inspections of each establishment and the examination of their stock vaccines, the license of one firm, which had expired, was not renewed, and the license of the other was suspended, both in accordance with the act of July 1, 1902. The licenses were renewed April 15.

All other licensed establishments were specially inspected and their vaccine virus was examined and found to be free from infection.

The subject was brought before the advisory board of the Hygienic Laboratory for its consideration and advice. The infection, in all probability, came from abroad, thus indicating the necessity of additional regulations relating to foreign importations.